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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,526	12/05/2001	Richard J. Massey	100390-6370	3441

35745 7590 01/05/2005

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EXAMINER

CEPERLEY, MARY

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,526

Applicant(s)

MASSEY ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2) Claims 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no indication in the specification at page 40, line 18 through page 42, line 2 of the specification (cited by applicants) that the "electrochemiluminescence co-reactant" is either "an amine" or "a reductant". Further, page 41, line 7 through page 42, line 2 of the specification describes the presence of an amine in an ECL reaction but provides no description of the amine being "attached to said carbon nanotube" as required by the claim language.

3) Claims 19-41 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the terms "substance" and "electrochemiluminescence co-reactant" for the reasons set forth in paragraph **4)** of the June 17, 2004 Office action. Applicants' arguments filed October 18, 2004 have been fully considered but they are not persuasive.

Applicants' reliance on the dictionary definition of "a material of a particular kind or constitution" to define the term "substance" does not overcome the fact that this term was not used in the specification. Given the *non-substantive* dictionary definition of this term, it is unclear what is meant to be encompassed by this term and it is not clear that "the inventors at the time the application was filed, had possession of the claimed invention", i.e. that the inventors had determined what "substances" were included in the invention. Although applicants offer to substitute the term "a composition comprising" for the term "substance" to overcome this rejection, they have provided no citation to the specification to support the substitution of one term for the other.

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Applicants rely on the description of pages 40 and 41 of the specification and Examples 10 and 11 to provide descriptive support for the term "electrochemiluminescence co-reactant". However, these portions of the specification which provide descriptions of *specific reactants* do not specifically state that these reactants are "electrochemiluminescence co-reactants" nor do they indicate what the more *general* term "electrochemiluminescence co-reactant" is meant to include.

4) Claims 19-41 are again rejected under 35 U.S.C. 112, first paragraph, for the reasons stated in paragraph **5)** of the June 17, 2004 Office action. Contrary to the statement made in the first paragraph of paragraph **II.** of the October 18, 2004 response, this rejection has been made as a *scope of enablement* rejection rather than a rejection involving *no enablement*. As pointed out in paragraph **5)** of the June 17, 2004 Office action, certain configurations of reactive components on the nanotube are required for the composition to be useful for the stated purpose of the invention.

5) Claims 19-41 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The paragraph numbers below correspond to those used in paragraph **6)** of the June 17, 2004 Office action.

a) Applicants' statement that the search of the USPTO database yields many hits on the term "substance" does not address the fact that exactly what is meant to be encompassed by this term cannot be determined either from a reading of the specification or from a dictionary definition of this term (see the dictionary definition provided in paragraph **I.A.** of the October 18, 2004 response).

Although applicants state that "one of ordinary skill in the art would readily understand what type of reaction is involved", presumably electrochemiluminescence, the term "electrochemiluminescence co-reactant" is not defined in the specification (Office action of June

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17, 2004, paragraph 4)) and there is no indication in the specification of what compounds are considered to be ECL "co-reactants".

b) The relative configuration of the "nanotube", "electrochemiluminescence co-reactant" and "electrochemiluminescent label" of claim 19 cannot be determined. The composition of claim 19 includes the case in which the ECL label is covalently attached directly to the ECL co-reactant and the case in which the ECL label is attached to the inside of the nanotube while the ECL co-reactant is attached on the outside of the nanotube. It is not clear that these configurations would be operable for the purpose of the invention.

c) This rejection could be overcome by reciting the term "enzyme substrate" (response of October 18, 2004, paragraph (d)).

e) This rejection is maintained for the reasons of record. Without the recitation of the essential method steps, the analytical method would not operate. There can be no "detecting" of an analyte by merely "contacting said sample" with "the substance of claim 19" without any requirement for *a binding/reaction of the analyte with another reactant* which would trigger a detectable ECL response which could be correlated with the presence/amount of analyte in the sample.

6) Claims 19-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the corresponding claims of U.S. Patent No. 5,866,434 for the reasons stated in paragraph 8) of the June 17, 2004 Office action. As described in paragraph 8) of the Office action, the composition of claim 18 of the patent describes a nanotube linked to "an electrochemiluminescent label" and "an enzyme"; this composition is clearly inclusive of the "nanotube" which has "a chemiluminescence co-reactant" (an enzyme) and "an electrochemiluminescent label attached" as claimed in instant claim 19. Applicants' statement that "one of ordinary skill in the art would not consider an ECL co-reactant to be an obvious variant of either an enzyme or enzyme co-factor"

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appears to be inconsistent with the state of the art as described at col. 49, line 63 – col. 50, line 10 of US 5,866,434 which indicates that enzymes and co-factors are well known “electrochemiluminescence co-reactants”.

7) Applicants’ amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at .

866-217-9197 (toll-free).

January 04, 2005

A handwritten signature in cursive script that reads "Mary E. Ceperley".

Mary (Molly) E. Ceperley
Primary Examiner
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